REMARKS/ARGUMENTS

This amendment is filed in response to the office action mailed August 5, 2008. A petition for a one-month extension of time is submitted herewith.

Claim 1 has been amended to recite that the high molecular weight coating polymer has a molecular weight of greater than about 300 kD. Support for this amendment may be found in original claim 5, which has been cancelled. Claim 7 has also been canceled.

Rejections under 35 U.S.C. 103(a)

Examiner has rejected claims 1-3, 6, 8, 52-54, 56-59, 61 and 62 under 35 U.S.C. 103(a) as being unpatentable over Winterton et al. (US 6,719,929) in view of Martin et al (US6,039,899). Claims 2-3, 6, 8, 52-54, 56-59, 61 and 62 all depend, either directly or indirectly, from claim 1.

Winterton et al. discloses a method for coating contact lenses with polyionic material(s) via applying the coating to the mold before forming a lens therein. Abstract. Winterton et al. disclose that the polyionic materials "will typically have a molecular weight Mn of about 10,000 to about 150,000" and that "if the increase in molecular weight is too substantial, the difficulty in handling may also increase." Column 13, lines 62-63 and 59-61 respectively. Thus, Winterton et al. specifically teaches away from coating materials having molecular weights substantially greater than 150,000 to avoid "difficulty in handling". Winterton et al. also fails to disclose a desired dwell time.

Martin et al. discloses apparatus and processes for making contact lenses. Martin et al. does not disclose or suggest any process or conditions for forming a coated lens. Martin et al. is silent as to the properties, such as molecular weight, for a coating material.

Claim 1 has been amended to recite that the coating polymer has a molecular weight of greater than about 300 kD. Accordingly, Applicants respectfully submit that the rejections based upon the combination of Winterton et al. and Martin et al. have been traversed, as neither Winterton et al., nor Martin et al. suggest coating polymers of the molecular weight recited onto a lens mold, or the conditions necessary to cure such coated lenses.

Examiner has also rejected claims 5 and 7 under 35 U.S.C. 103(a) as being unpatentable over Winterton et al. (US 6,719,929) in view of Martin et al (US6,039,899) and Vanderlaan et al (US6,087,415). As claim 1 now contains the recitation of claim 5, Applicants respond as if the rejection had been made against claim 1, and the claims that depend therefrom.

Vanderlaan et al. discloses "contacting at least one surface of a medical device with a coating effective amount of a carboxyl-functional polymer and . . . at least ***one coupling agent***". Column 1, lines 39-42. (emphasis added). Preparation 1, column 6, lines 1-10, discloses making an uncoated silicone hydrogel contact lens, which is then coated by contacting the formed lens with a coating solution and a coupling agent (Example 1). Vanderlaan et al. does not disclose nor suggest any of the following elements recited in claim 1:

(a) coating compositions which do not chemically attach to the substrate,

(b) coating a molding surface with a high molecular weight coating composition;

(c) dispensing a monomer mixture comprising, a silicone-containing hydrogel monomer, into the coated mold or mold half; and

(d) curing the monomer mixture and the coating composition using a dwell time of less than about 5 minutes and under conditions suitable to form an article coated with the coating composition.

As discussed above, Winterton et al. at column 13, lines 59-61, specifically warns against using coating materials having molecular weights substantially greater than 150,000 because of the increased "difficulty in handling". Claim 1, as amended, recites that the coating polymer have a molecular weight "greater than about 300 kD", which is *twice* the highest molecular weight disclosed in Winterton et al. Examiner has sought to cure this deficiency by replacing the molecular weight range disclosed by Winteron et al. with the range disclosed in Vanderlaan et a. However, Vanderlaan et al. discloses a completely different coating process (treating a formed lens with a coupling agent and a coating polymer) than Winterton et al. (treating a mold with a non-reactive polyionic polymer). There is nothing in either patent which would suggest that the conditions disclosed in one would be interchangeable with those of an entirely different process. In fact, Winterton et al. clearly discloses that most of the molecular weight range disclosed in Vanderlaan et al. would not be suitable in the Winterton et al. process because 'the difficulty in handling may increase' as the molecular weight increases above 150,000.

> "It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one skilled in the art." *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.,* 796 F.2d 443; 230 U.S.P.Q. 416 (Fed. Cir. 1986)

Accordingly, Applicants respectfully submit that the combination of Winterton et al. and Vanderlaan et al. do not suggest claim 1 as currently amended, or any of dependent claims 2-3, 6, 8, 52-54, 56-59, 61 and 62 that depend therefrom.

With respect to claim 7, Martin et al. is silent as to any process for making a coated contact lens, the desired properties of the coating polymer (such as molecular weight), or curing conditions for the coated lens (such as a dwell time of less the 45 seconds). Martin instead discloses automated method and apparatus for the continuous or semi-continuous production of contact lenses.

As noted in the prior response, Martin et al. also discloses

> "Accumulator section 168 includes a holding mechanism 166 that is timed by a control means (not shown) to halt a lead pallet in place on the conveyor 32(c) and enable a predetermined number of subsequent pallets to assemble behind the halted lead pallet to enable batch processing at the procure apparatus. In the preferred embodiment, twelve pallets are accumulated enabling up to ninety-six (96) mold assemblies to be processed at the precure apparatus 60 in a batch mode for an extended period of time of 30 to 60 seconds while continuously receiving new pallets from the production line at a rate of 1 every 6 to 12 seconds." Column 32, lines 51-65.

The purpose of the accumulator is to ***delay*** the pallets from entering the cure tunnel. This delay insures that the pallets being accumulated do not push the pallets already in the cure tunnel out before they are done, or do not create a jam in front of the cure tunnel which would result in pallets being pushed from conveyor. Had Martin et al. appreciated the criticality of the dwell time specified in the present application, they clearly would not have suggested an intentional ***delay*** in curing the mold assemblies. Applicants also note that Martin et al. does not disclose how long it takes to get the lenses from the filling step 107 to the curing step 110, and that the other steps, such as clamping and transporting the mold assemblies need to be considered in determining the dwell time of the Martin et al. process. Martin et al. does not disclose how long these steps take.

According to Martin et al. the accumulator holds new pallets until 12 are accumulated. If pallets arrive every 6 to 12 seconds, that means the lenses can be held at the accumulator from between 72 to 144 seconds. Examiner has stated that the "timeframe takes the maximum number of lenses suggested by Martin et al, into account ("up to ninety-six"). In this "up-to" embodiment, about half of the lenses would continue to have a dwell time of less than about 45 seconds." What Martin et al. says is:

"twelve pallets are accumulated enabling ***up to ninety-six (96) mold assemblies*** to be processed at the precure apparatus". Col. 32, lines 61-62. The phrase "up to" refers to the number of mold assemblies in each pallet, not the number of pallets being collected in the accumulating section. Even if each pallet is half full, the lenses will still be held in the accumulating section for the time periods disclosed in Martin et al. (72 to 144 seconds).

The cited references recognize neither the problem nor the solution identified by the Applicants, namely that "[d]well time, or the elapsed time from which the monomer mixture is dispensed into the mold until curing commences is critical because the coating composition is soluble in the hydrogel and silicone-containing hydrogel monomer mixtures." Page 16, lines 28-31.

It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992). At best, the Action has proffered a collection of references that mention the various elements in isolation. This, however, does not establish a legally sufficient *prima facie* obviousness rejection. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, (2007) ("[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.").

Applicants respectfully submit that claim 7 is patentable over the combination of Winteron, et al., Vanderlaan et al. and Martin et al.

Examiner further rejected claims 9 and 10 as unpatentable over Winterton et al. in view of Martin et al. and Li et al (US 6,565,776).

Li et al discloses "using inorganic material to coat the optical surfaces and sidewalls of mold parts made from clear-resin materials". The coating materials protect "the clear resin from interaction with otherwise reactive monomers from which the molded article is made, such coatings can also be used to achieve preferential release." Li et al. abstract. Thus the coatings of Li et al. remain on the lens mold and do not become part of the contact lens. Li et al. discloses neither processes for making coated contact lenses, coating polymers having the specified molecular weights nor the recited dwell times. Thus, Li et al. does not cure the deficiencies of the previously discussed references.

Examiner further rejected claim 11 as unpatentable over Winterton et al. in view of Martin et al. and Soye et al (US 5,316,700). Claim 11 depends indirectly from claim 1.

Soye et al. et al discloses "providing [a] cavity for excess lens forming material with at least two openings and producing differential gas pressure across the opening to remove excess lens forming material." Soye et al. abstract. Soye et al. does not disclose methods for forming coated contact lenses, the desired molecular weights for the coating polymer or dwell times useful therefore. Thus, Soye et al. does not cure the deficiencies of the previously discussed references.

Examiner further rejected claims 14-18, 23, 64-66, 68-71 and 74 as unpatentable over Winterton et al. in view of Martin et al. and Yang et al (US5,397,848) and Lohmann et al (US 6,169,127).

Winterton et al. specifically discloses that the coatings described therein are polyionic. PolyHEMA is a non-ionic polymer.

Examiner stated that Yang et al. "suggest poly(acrylic acid), poly(methacrylic acid) and poly(hydroxyethyl methacrylate) are suitable and equivalent alternative hydrophilic materials." Applicants respectfully disagree. Yang et al. discloses that poly(acrylic acid), poly(methacrylic acid) and poly(hydroxyethyl methacrylate) are examples of hydrophilic moieties which may be used as the hydrophilic portion of a silicone-hydrophilic copolymer. See col.1, lines 63-66 which discloses processes "for incorporating a hydrophilic constituent into a silicone polymer material comprise introducing a hydrophilic component including a hydrophilic portion and a silicone portion into a silicone polymeric material." "It is believed that the silicone polymer portion of the presently useful hydrophilic constituents, e.g., the hydrophilic component itself, often have sufficiently high molecular weight so as to facilitate the physical immobilization of the hydrophilic component in the silicone polymer material." Col. 3, lines 27-31. Thus Yang et al. does not disclose polyHEMA as suggested by the Examiner, but instead silicone-polyHEMA copolymers, which contain "silicone polymer portions of sufficiently high molecular weight so as to facilitate physical immobilization." Silicone-polyHEMA copolymers of this type are not recited in claim 14.

Lohman et al. discloses coating an article via "after-glow plasma-induced polymerization of a ***polymerizable unsaturated*** compound on the substrate". Col. 7, lines 4-5. Lohman et al. teaches that the "expressions 'polymerizable unsaturated compound' and monomer are used . . . synonymously". Col 7, lines 23-25. Lohman et al. further discloses at

column 11, lines 5-15 that hydroxyethylmethacrylate is a suitable monomer which may be used in the after- glow plasma-induced coatings disclosed therein. Thus, Lohman et al. discloses a reactive process for forming coatings from ***reactive monomers***. Lohman et al. also discloses that the substrate "includes any material conventionally used for the manufacture of biomedical devices, e.g. contact lenses, which are hydrophilic per se, sins reactive groups, e.g. amine or hydroxyl groups are inherently present in the material and therefore also at the surface of a biomedical device . . . but suitable materials may also be based on other underlying monomers or polymers having reactive groups." Column 10, lines 16-29. Thus, there is nothing in Lohman et al. which suggests using any polymeric material as a coating componsition. Instead Lohman et al. discloses forming a polymeric coating, by polymerizing reactive monomers onto a lens surface which has reactive groups.

Winterton et al. requires that the coating compositions disclosed therein contain at least one polyionic material. "As used herein, a 'polyion' or 'polyionic material' refers to a polymeric material that has a plurality of charged groups". Col. 9, lines 22-24.

Winterton et al. discloses that the polyionic materials are critical as, to build coatings having the desired thickness, multiple coatings having alternating charges are used. See, for example, column 3, lines 32-47. PolyHEMA is a non-ionic polymer. Yang et al. and Lohmann et al. disclose that polyHEMA is a hydrophilic polymer. However, there is nothing in either Yang et al. or Lohman et al. which would suggest that polyHEMA is equivalent to ionic polymers such as poly(methacrylic acid) or poly(acrylic acid) when an ioinic polymer required.

Claims 15-18, 23, 64-66, 68-71 and 74 all depend from claim 14, and are patentable for the reasons discussed above. Applicants respectfully submit that the Examiner has not made a legally sufficient *prima facie* rejection, and Applicant respectfully requests that the rejections of claims 14, 15-18, 23, 64-66, 68-71 and 74 under 35 U.S.C. § 103(a) be withdrawn.

Examiner has further rejected claims 19 and 20 as unpatentable over Winterton et al. in view of Martin et al. and Yang et al., Lohmann et al., and in further view of Turner et al. (WO 01/27662).

Claims 19 and 20 depend indirectly from claim 14, and are thus patentable for all the reasons discussed above. Turner et al. discloses that the "coatings are prepared and applied as aqueous solutions, suspensions, or colloids and then applied to the substrate", page 8, lines 5-7. Thus, regardless of the substrate polymers disclosed by Turner et al., its disclosure does not cure the deficiencies of the combination of Winterton et al., Martin et al., Yang et al, Lohmann et al.

Applicants submit claims 9 and 10 are therefore patentable over the cited combination of references, as the references fail to suggest using polyHEMA to coat a lens mold and form a coating which is not chemically attached to the lens.

Examiner further rejected claims 24 and 25 as unpatentable over Winterton et al. in view of Martin et al., Yang et al. Lohmann et al and Li, stating that Li discloses that spin coating is a recognized technique for coating a contact lens mold. Claims 24 and 25 depend indirectly from claim 14. Even if Li et al. is taken to disclose spin coating as a recognized technique, as discussed above with respect to claim 14, the combination of Winterton et al., Martin et al., Yang et al. and Lohmann et al. fail to suggest using polyHEMA to coat a lens mold and form a coating which is not chemically attached to the lens. Accordingly, claims 24 and 25 are patentable for the same reasons as claim 14.

Examiner further rejected claim 26 as unpatentable over Winterton et al. in view of Martin et al., Yang et al. Lohman et al., Li et al. and Soye et al. Claim 26 depends indirectly from claim 14. As discussed above with respect to claim 14, the combination of Winterton et al., Martin et al., Yang et al. and Lohman et al. fail to suggest using polyHEMA to coat a lens mold and form a coating which is not chemically attached to the lens. Soye et al. does not disclose any of these elements. Accordingly, claim 26 is patentable for the same reasons as claim 14.

Examiner further rejected claims 31,32,36,38,76-78, 80-83, 85 and 86 as unpatentable over Winterton et al. in view of Martin et al. and Vanderlaan et al.

Claim 31 recites that hydrophilic coating composition having a molecular weight of greater than about 300 kD; a dwell time of less than about 45 seconds and said coating composition does not chemically attach to the article.

As discussed above with respect to amended claim 1, the references taken as a whole fail to discuss a process having the recited combination of coating molecular weight, dwell time and lack of chemical attachment. Moreover, the Examiner's assumptions about what Winterton et al. teaches about the selection of molecular weight and the "dwell times" inherently possessed by Martin et al. have been clearly rebutted above. Applicants respectfully submit that a prima facie case of obviousness has not been made. Withdrawal of the rejections based upon claims 31, 32, 36, 38, 76-78, 80-83, 86 and 86 is requested.

Examiner has rejected claims 34 and 35 as unpatentable over Winterton et al. in view of Martin et al. and Vanderlaan et al. and Turner et al.

Claims 34 and 35 depend indirectly from claim 31, and are thus patentable for all the reasons discussed above. Turner et al. discloses that the "coatings are prepared and applied as aqueous solutions, suspensions, or colloids and then applied to the substrate", page 8, lines 5-7. Thus, regardless of the substrate polymers disclosed by Turner et al., its disclosure does not cure the deficiencies of the combination of Winterton et al., Martin et al. and Vanderlaan et al. Applicants submit claims 34 and 35 are therefore patentable over the cited combination of references.

Examiner has rejected claim 37 as unpatentable over Winterton et al. in view of Martin et al. and Vanderlaan et al., Yang et al. and Holguin et al. (US6,706,836). Holguin et al. discloses a method for preparing poly 2-hydroxyethyl methacrylate and pressure sensitive adhesives. There is nothing in Holguin et al. which would suggest that a non-ionic polymer such as polyHEMA could be used in a coating process where an ionic polymer is required, or that a polymer having a molecular weight twice that disclosed in Winterton et al. would be useful in that process. Accordingly, claim 37 is patentable over the combination of Winterton et al. in view of Martin et al., Vanderlaan et al., Yang et al. and Holguin et al.

Examiner has rejected claims 39 and 40 as unpatentable over Winterton et al. in view of Martin et al., Vanderlaan et al. and Li et al. and claim 41 as unpatentable over Winterton et al. in view of Martin et al., Vanderlaan et al., Li et al. and Soye et al. Claims 39, 40 and 41 depend indirectly from claim 31. As discussed above with respect to claim 31, the combination of Winterton et al., Martin et al. and Vanderlaan et al. fail to suggest coating processes comprising hydrophilic coating composition having a molecular weight of greater than about 300 kD which are coated on a mold surface; a dwell time of less than about 45 seconds and said coating composition does not chemically attach to the article. Neither Soye et al. nor Li et al. disclose any of these elements. Accordingly, claims 39, 40 and 41 are patentable for the same reasons as claim 31.

Examiner has rejected claims 55, 60 and 63 as unpatentable over Winterton et al. in view of Martin et al., and Narducy et al. (US 4,963,159). In making the rejection Examiner

applied Winterton et al. and Martin et al. as applied to claim 1 and cited Nardurcy et al. as a reference to disclose ethanol as a solvent and ethyl lactate as a cosolvent. Claims 55, 60 and 63 depend indirectly from claim 1, which has been amended to recite that the coating polymer has a molecular weight of greater than about 300 kD. Narducy et al. neither discloses nor suggests this. Thus, claims 55, 60 and 63 are patentable for the reasons discussed above with respect to claim 1.

Examiner has rejected claims 67, 72 and 75 as unpatentable over Winterton et al., Martin et al., Yang et al, Lohmann et al. and Narducy et al. In making the rejection Examiner applied Winterton et al., Martin et al., Yang et al, Lohmann et al as applied to claims 14-18, 23, 64-66, 68-71, 73 and 74 and cited Nardurcy et al. as a reference to disclose ethanol as a solvent and ethyl lactate as a cosolvent. Claims 67, 72 and 75 depend indirectly from claim 14. As discussed above with respect to claim 14, Winterton et al. requires the polymers used in its coating process are polyioinic. PolyHEMA is a non-ionic polymer, and there is nothing in either Yang et al. or Lohmann et al. which would suggest that polyHEMA is equivalent to ionic polymers such as poly(methacrylic acid) or poly(acrylic acid) when an ioinic polymer is required. Narducy et al. does not cure this deficiency. Accordingly, claims 67, 72 and 75 are patentable for the reasons discussed with respect to claim 14.

Examiner rejected claims 79, 84 and 87 as unpatentable over Winterton et al., Martin et al., Vanderlaan et al. and Narducy et al. as applied to claims 31, 32, 36, 38, 76-78, 80-83, 85 and 86 and cited Nardurcy et al. as a reference to disclose ethanol as a solvent and ethyl lactate as a cosolvent.

As discussed above with respect to amended claim 1, the references taken as a whole fail to discuss a process having the recited combination of coating molecular weight, dwell time and lack of chemical attachment. Narducy et al. does not cure this deficiency. Accordingly, claims 79, 84 and 87 are patentable for the reasons discussed with respect to claims 31, 32, 36, 38, 76-78, 80-83, 85 and 86.

Conclusions

Applicants respectfully submit that the foregoing arguments and amendments have traversed the Examiner's rejections. Withdrawal of the rejections and allowance of the claims as amended is

respectfully requested. If the Examiner is of a contrary view, the Examiner is requested to contact the undersigned attorney at (904) 443-3074.

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